

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial comparing pregnancy rate between fresh and frozen embryo transfer cycles in women with endometriosis: a pilot Study

Protocol summary

Summary

Objectives: endometriosis is a common condition that affects 10–15% of all women during the reproductive years. Endometriosis is a major cause of infertility and may be present with no symptoms. In vitro fertilization (IVF) offers the highest chance of pregnancy for subfertile women with endometriosis. The aim of our study is to evaluate the reproductive outcomes of frozen-thawed embryo transfers (ET) cycles compared to fresh embryo transfer cycles, in women with endometriosis. Design: in this randomized controlled pilot study a total of 60 infertile women with endometriosis who will be referred to Royan Institute will be recruited. Setting and conduct: all subjects underwent conventional controlled ovarian stimulation using a ultra-long protocol. After puncture the patients will be divided in to two groups of study and control. In the study group embryos will be frozen for 2 months. Gonadotropin also is used for 2 months in order to prepare the endometrium. Then hormonal replacement therapy will be performed and followed by frozen-thawed embryo transfer. In control group, the fresh embryos will be transferred. Participants including major eligibility criteria: women with well-known predisposing factors for implantation failure such as thrombophilia, underlying immune conditions, uterine malformation (i.e. didelphys, septate, bicornuate or hypoplastic uterus); parental chromosomal abnormalities; severe male factor infertility; cancelled cycles which did not result in embryo transfers and women with frozen embryos in which their cycles had been canceled due to thin endometrial thickness. Intervention: The women will be randomly divided into two groups of frozen-thawed embryo transfer and fresh embryo transfer. Main outcome measures: Clinical pregnancy rate outcome will be compared between 2 groups. To confirm the pregnancy, the patients will be tested for serum β -hCG, 14 days after embryo transfer. Vaginal sonography will be done 2 weeks after the positive result of pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608171141N21**

Registration date: **2016-08-26, 1395/06/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-26, 1395/06/05

Registrant information

Name

Kiandokht Kiani

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2230 7960

Email address

kiandokht.kiani@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Royan Institute

Expected recruitment start date

2014-01-30, 1392/11/10

Expected recruitment end date

2015-08-01, 1394/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing pregnancy rate between fresh and frozen embryo transfer cycles in women with endometriosis: a pilot Study

Public title

Comparison of pregnancy rate between fresh and frozen embryo transfer cycles in women with endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: infertile patients with endometriosis; age ≤ 35 years; at least one endometrioma diagnosed by sonography or confirmed by laparoscopy; history of one failed in vitro fertilization failure (IVF). Exclusion criteria: women with well-known predisposing factors for implantation failure such as thrombophilia, underlying immune conditions, uterine malformation (i.e. didelphys, septate, bicornuate or hypoplastic uterus); parental chromosomal abnormalities; severe male factor infertility; cancelled cycles which did not result in embryo transfers; women with frozen embryos in which their cycles had been canceled due to thin endometrial thickness.

Age

To 35 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Royan Institute

Street address

Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-09-25, 1391/07/04

Ethics committee reference number

EC/91/1085

Health conditions studied

1

Description of health condition studied

Endometriosis of ovary

ICD-10 code

N80.1

ICD-10 code description

Endometriosis of ovary

Primary outcomes

1

Description

Clinical pregnancy rate

Timepoint

4-6 weeks after embryos transfer (ET)

Method of measurement

Vaginal sonography

Secondary outcomes

1

Description

Implantation rate

Timepoint

4-6 weeks after embryos transfer (ET)

Method of measurement

Vaginal sonography

2

Description

Ongoing pregnancy rate

Timepoint

Pregnancy after 12 weeks of gestation

Method of measurement

Vaginal sonography

3

Description

Miscarriage rate

Timepoint

Abortion before 12 weeks of gestation

Method of measurement

Vaginal sonography

Intervention groups

1

Description

Intervention/ Control: In the intervention group, embryos will be frozen for 2 months. Gonadotropin also is used for 2 months in order to prepare the endometrium. Then hormonal replacement therapy will be performed and followed by frozen-thawed embryo transfer.

Category

Treatment - Other

2

Description

Intervention/ Control: In control group, the fresh embryos will be transferred.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Nadia Jahangiri

Street address

Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Nadia Jahangiri

Street address

Royan Institute, Number 12, East Hafez Avenue, Bani Hashem Street, Resalat high way, Tehran, Iran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Royan Institute

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Nadia Jahangiri

Position

MS of midwifery / principal investigator

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Tahereh Madani

Position

Gynecologist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Nadia Jahangiri

Position

MS of midwifery / principal investigator

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty